JUN 8 - 2005

10. 510(k) SUMMARY

This summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The Assigned 510(k) number is K050878

Submitter:

ACON Laboratories, Inc.
4108 Sorrento Valley Boulevard
San Diego, California 92121

Tel.: 858-535-2030
Fax: 858-535-2038

Date:

April 4, 2005

Contact Person:

Edward Tung, Ph.D.

Product Names:

On-Call™ Multi-Drug Home Test Cup for Marijuana, Cocaine, Amphetamine, Methamphetamine, Ecstasy, Opiates, and Phencyclidine

Common Name:

Immunochromatographic test for the qualitative detection of Marijuana, Cocaine, Amphetamine, Methamphetamine, Ecstasy, Opiates, and Phencyclidine in urine.

Regulation Name:

Marijuana, Cocaine, Amphetamine, Methamphetamine, Ecstasy, Opiates, and Phencyclidine test system.

Product Code:

LDJ, DIO, DKZ, LAF, DJG, LCM

Classification Number:

21 CFR 862.3870, 21 CFR 862.3250, 21 CFR 862.3100, 21 CFR 862.3610, 21 CFR 862.3650

Device Classification:

The Marijuana, Cocaine, Amphetamine, Methamphetamine, Ecstasy, Opiates, and Phencyclidine test systems have been classified as Class II devices with moderate complexity. The On-Call™ Multi-Drug Home Test Cup is similar to another FDA-cleared device (ACON Spectrum Multi-Drug Multi-Line Drug Screen Test, K031759) for the qualitative detection of Marijuana, Cocaine, Amphetamine, Methamphetamine, Ecstasy, Opiates, and Phencyclidine in urine specimens. This test is used to provide only a preliminary analytical result. All positive test results obtained with these devices must be confirmed by another test method, preferably GC/MS analysis.

Statement of Intended Use Compared to Other Products:

The On-Call™ Multi-Drug Home Test Cup is a rapid lateral flow immunoassay for the qualitative detection of drugs in urine at a cutoff concentration of 50 ng/mL for Marijuana, 300 ng/mL for Cocaine, 1,000 ng/mL for Amphetamine, 1,000 ng/mL for Methamphetamine, 500 ng/mL for Ecstasy, 2,000 ng/mL for Opiates, and 25 ng/mL for Phencyclidine. This test is used to provide only a preliminary analytical result. All positive test results obtained with these devices must be confirmed by another test method, preferably GC/MS analysis. They are intended for the over-the-counter lay person use.

Discussion of Technological Characteristics:

The On-Call™ Multi-Drug Home Test Cup is a competitive binding, lateral flow immunochromatographic assay for the qualitative screening of Marijuana, Cocaine, Amphetamine, Methamphetamine, Ecstasy, Opiates, and Phencyclidine in a urine sample. The test is based on the principle of antigen-antibody immunochemistry. It utilizes the mouse monoclonal antibody to selectively detect elevated levels of drugs, and their metabolites in urine at a cutoff concentration of 50 ng/mL for Marijuana, 300 ng/mL for Cocaine, 1,000 ng/mL for Methamphetamine, 500 ng/ml for Ecstasy, 2,000 ng/mL for Opiates, and 25 ng/mL for Phencyclidine. This test can be performed without the use of an instrument.

A drug-positive urine specimen will not generate colored-lines in the designated test region, while a negative urine specimen or a urine specimen containing Marijuana, Cocaine, Amphetamine, Methamphetamine, Ecstasy, Opiates, or Phencyclidine at the concentration below the cutoff level will generate colored-lines in the test region. To serve as a procedural control, a colored-line should always appear at the control region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

Safety and Effectiveness Data:

Because the On-Call™ Multi-Drug Home Test Cup is identical to the ACON Key Cup (K031759) that is legally marketed for professional use; and because no special skills, training, education, or licensing is required to transfer a few drops of a urine sample into the test card well, there is no issue regarding the safety or effectiveness of the product to perform its intended function, i.e., to screen urine for the presence or absence of THC, COC, AMP, mAMP, MDMA, OPI, PCP, and their metabolites. The labeling of the On-Call™ Multi-Drug Home Test Cup is similar to a variety of rapid screening tests currently in commercial distribution in the U.S., including the Phamatech At Home™ Drug Test. There have been no reports of consumer inability to follow instructions or interpret results over the many months these products have been marketed, it should be concluded that the product can be used effectively by a lay user.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 8 - 2005

Edward Tung, Ph.D.
Regulatory Affairs
ACON Laboratories, Inc.
4108 Sorrento Valley Blvd.
San Diego, CA 92121

Re: k050878
Trade/Device Name: On-Call™ Multi-Drug Home Test Cup for Marijuana, Cocaine, Amphetamine, Methamphetamine, Ecstasy, Opiates and Phencyclidine
Regulation Number: 21 CFR 862.3870
Regulation Name: Cannabinoid test system
Regulatory Class: Class II
Product Code: LDJ, DIO, DKZ, LAF, DJG, LCM
Dated: April 4, 2005
Received: April 6, 2005

Dear Dr. Tung:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Carol C. Benson

Carol C. Benson, M.A.
Acting Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

13. **INDICATIONS FOR USE**

510(k) Number (if known): K050878

Device Name: On-Call™ Multi-Drug Home Test Cup for Marijuana, Cocaine, Amphetamine, Methamphetamine, Ecstasy, Opiates, and Phencyclidine

Indications for Use:

The On-Call™ Multi-Drug Home Test Cup is a screening test for the rapid detection of drugs in urine at a designated cut-off concentration of 50 ng/mL for Marijuana, 300 ng/mL for Cocaine, 1,000 ng/mL for Amphetamine, 1,000 ng/mL for Methamphetamine, 500 ng/mL for Ecstasy, 2,000 ng/mL for Opiates, and 25 ng/mL for Phencyclidine. The test is intended for over-the-counter (OTC) consumer use.

This assay provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated.

Prescription Use _____ AND/OR Over-The-Counter Use __X__
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Ruth a chesler

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K050878